JAN 24 2000 P.

8 mf 3/20/03

Attorney Docket No. 402091/SKYEPHARMA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MISHRA et al.

Group Art Unit: 1617

Application No. 09/820,371

Examiner: E. Webman

Filed: March 26, 2001

For:

INJECTABLE AQUEOUS DISPERSIONS

OF PROPOFOL

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, D.C. 20231

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

within any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

01/ES/2003 EAREGAY1 00000005 121216 09820371

31 FD:1808

180.00 CH

In re Appln. of Mishra et al. Application No. 09/820,371

| \boxtimes | 37 CF | (a), (b), (c) or (d) above, but before the mailing date of a final action under R 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that vise closes prosecution in the application, and includes <i>one</i> of: |
|-------------|--|---|
| | | the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below). |
| | $\overset{or}{oxtimes}$ | the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below). |
| | under and o 37 CF | the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance 37 CFR 1.311, or an action that otherwise closes prosecution in the application, n or before payment of the issue fee, and includes the Statement under R 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as th in 37 CFR 1.17(p) (see "Fees" below). |
| | payme contain 37 CF \$180 a NOTE: May 29 | the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before ent of the issue fee, and within thirty days of receiving each item of information ned in the Information Disclosure Statement, and includes the Statement under R 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of its set forth in 37 CFR 1.17(p) (see "Fees" below). This is for original applications except applications for a design patent, filed on or after 2000, wherein a paper containing only an Information Disclosure Statement in compliance CFR 1.97 and 1.98 is being filed. |
| Copie | s of the | References |
| | Attach releval an Engaction degree | s of the references listed on the enclosed Form 1449 are enclosed herewith. Led to each reference not in the English language is a concise explanation of the name pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or glish-language abstract, or an English-language version of the search report or by a foreign patent office in a counterpart foreign application indicating the cof relevance found by the foreign office is being submitted in lieu of a concise nation of the relevance pursuant to 37 CFR 1.98(a)(3). |
| | A copy | y of the foreign search report is enclosed herewith. |
| ⊠ < | furnish submit The I accord Proced relied | eferences listed on the enclosed Form 1449 were previously identified in the application(s) of the present application, and copies of the references were ned at that time. Accordingly, additional copies of the references are not ted herewith, so as not to burden the file with duplicate copies of references. Examiner is respectfully requested to carefully review the references in lance with the requirements set out in the Manual of Patent Examining lure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) upon for an earlier filing date under 35 USC 120 in which copies of the nees were previously furnished are set out below: |

In re Appln. of Mishra et al. Application No. 09/820,371

| U.S. APPL | U.S. APPLICATIONS | | | ne) |
|-------------------------------|-------------------|----------|---------|-----------|
| U.S. APPLICATIONS | U.S. FILING DATE | PATENTED | PENDING | ABANDONED |
| 1. 09/376,487 August 18, 1999 | | | X | |
| 2. | | | | |
| 3. | | | | |

| 2. | | | | | |
|-------|---|---|---|---|---|
| 3. | | | | | |
| State | nent under 37 CFR | 1.97(e) | | | |
| | Information Discletion foreign patent office | hereby states that each osure Statement was fince oe in a counterpart foreign filing of the Information | rst cited in a gn patent app | ny commun lication not r | ication from a |
| | Information Disclo office in a counte undersigned after n Information Disclo | hereby states that no sure Statement was cited erpart foreign patent appraising reasonable inquirusure Statement was known than three months int. | in a communication, and y, no item of any | ication from a , to the kno information o y individual | a foreign patent owledge of the contained in the designated in |
| State | nent under 37 CFR | 1.704(d) | | | |
| | Information Disclo office in a counter any individual desi | hereby states that each sure Statement was cited part application and that gnated in 37 CFR 1.56(c) Disclosure Statement. | in a communithis commun | ication from a ication was i | a foreign patent not received by |
| Fees | | | | | |
| | No fee is owed by the IDS Fee of \$13 | he applicant(s). 80 under 37 CFR 1.17(p) | is enclosed he | erewith. | |
| Meth | od of Payment of Fe | ees | | | |
| | | in the amount of \$ count No. 12-1216 in the is enclosed for that purp | | 80.00. (A dı | iplicate copy of |
| A 41 | · · · · · · · · · · · · · · · · · · · | A 3 3*4* 1 Tr | | | |

Authorization to Charge Additional Fees

If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

In re Appln. of Mishra et al. Application No. 09/820,371

Instructions as to Overpayment

Credit Account No. 12-1216.
Refund

Respectfully submitted,

Leah Robinson, Reg. No. 44,990 LEYDIG, VOIT & MAYER

700 Thirteenth Street, N.W., Suite 300

Washington, DC 20005-3960 (202) 737-6770 (telephone) (202) 737-6776 (facsimile)

Date:

LOR:ves

| Shee | t 1 | f 1 | | | 9 | | | |
|-------------------|--------------------------|-----------------------------|---------|------------------------------------|----------------|----------|--------------------|--------|
| PIN | EMPMA | TION DISCLOSURE | ATTY. D | OCKET NO. | SERIAL NO. | | | |
| () '''' | M Ellin | TION DISCLOSURE CITATION | 121- | 175 | 09/376,487 | | | |
| JAH 2 | JOIN A | / | MISI | HRA et al | | | | |
| SHEWI & T | T ADE TO SO | veral sheets if necessary) | FILING | • | GROUP | | | |
| <u>a</u> 1 | 11 | | Augi | ıst 18, 1999 | 1617 | | | |
| | | | | U.S. PATENT DOCUMENTS | | | | |
| *EXAMIN INITIA | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING IF APPRO | |
| | | 5,589,508 | 12/96 | Schlotzer et al | | | | |
| | | | | | | | | · · · |
| | | · ··· | | | | | | |
| | | | | | | | | |
| | _ | · | | | | | | |
| | | | | | L | | | |
| | | | F(| DREIGN PATENT DOCUMENTS | | | | |
| | | | | | | | | LATION |
| | | DOCUMENT | DATE | COUNTRY | CLASS | SUBCLASS | YES | NO |
| | | 0 770 387 A1 | 5/97 | Europe | | | | |
| | | | | | | | | |
| | | | | | | | | - |
| | | | | | | | | |
| | | | | / | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | <u></u> | | | | |
| | | OTHER DOO | UMENTS | (including Author, Title, Date, Pe | rtinent pages, | etc.) | | |
| | $\perp \perp \perp$ | | | | | | | |
| <u> </u> | | | | | | | | |
| <u> </u> | $-\downarrow \downarrow$ | | | | | | | |
| <u> </u> | | <u> </u> | | | | | ·· | |
| *Examir | ner | | | Date Considered | 1 1 | | | |
| | | | | | | | | |

Examiner. Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

| She t 1 | | | | | | | |
|--------------------|------------------------------|----------|---------------------------------------|-----------------|--|-------------------|--------------|
| INFORM | NATION DISCLOSURE | ATTY. DO | OCKET NO. | SERIAL NO. | | | _ |
| E. Joja | CITATION | 121-1 | | 09/376,487 | | • | |
| TOTO # | | APPLICA | | | | | |
| " JOHN BE | | | IRA et al | | | | |
| ST/s | several sheets if necessary) | FILING D | ATE | GROUP | · | | |
| TRADEMA | | Augu | st 18, 1999 | 1617 | | | |
| | | Ü | J.S. PATENT DOCUMENTS | | | | |
| XAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING IF APPR | D. |
| · I | 5,714,520 | 2/98 | Jones et al. | . | 1 | " AFFR | UF |
| | 4,056,635 | 11/77 | Glen et al. | · · | · . | | _ |
| | 5,637,625 | 6/97 | Haynes | | | | _ |
| | | | | | | | |
| | | | | | | <u> </u> | |
| | | | | ···· | | | . |
| | <u> </u> | | | | | | _ |
| | | | | | | | |
| | | | | | + | | |
| - | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | + | | *** | | | | _ |
| | | | | | | | |
| | | | | | | | _ |
| | | | | . | · · | | |
| | | | · · · · · · · · · · · · · · · · · · · | | | | |
| | | | | | | | |
| | | | | | | | |
| | | l | REIGN PATENT DOCUMENTS | | <u> </u> | | _ |
| | | | | | | TRANS | ĪĀ. |
| | DOCUMENT | DATE | COUNTRY | CLASS | SUBCLASS | YES | |
| | | | | | | | Г |
| | | | | | | | T |
| | | | | | | | T |
| | | • | | | | • | Г |
| | | | | | 1 | - | Г |
| | | | | | <u> </u> | _ | \vdash |
| | | | | | | · · · · · · · | r |
| | | | | | | | Ι. |
| I | OTHER DOC | JMENTS (| including Author, Title, Date, P | ertinent pages. | etc.) | | <u> </u> |
| | | | ent fat emulsion" Pharmaceutic | | | 98. | _ |
| 1 1 | pp 442-448 | | | | | • | |

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

*Examiner

Date Considered

Form PTO-FB-A820 (Also PTO-1449)





INFORMATION DISCLOSURE

ATTY. DOCKET NO.

SERIAL NO.

CITATION

121-175 APPLICANT 09/376,487

(Use Several sheets if necessary)

MISHRA et al

FILING DATE

GROUP

August 18, 1999

1617

DOCUMENT DATE COUNTRY CLASS SUBCLASS YES NO

FOREIGN PATENT DOCUMENTS

| | | | | | | | | | | 1 | | |
|-----|----------|-------------|----------|---------|-----------|-----------|-------------|------------|----------|-------|--------------|---|
| | | 1 1 | | | | | | | | | | |
| | | | | | | | | | 1 | 1 | - 1 | 1 |
| | | <u>1l,</u> | OTHER DO | CUMENTS | (includin | g Author, | Title, Date | , Pertinen | t pages, | etc.) | | |
| | | | | | | | | | | | , | |
| | | | | | | | | | | | | |
| | <u> </u> | 1 | | | | | | | | | | |
| | | | | | | | | | | | | |
| | 1 | | | | | _ | | | | | | |
| xar | miner | | | | | [| Date Consid | lered | | | | |
| _ | | | | | | | | | | | | |

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

| Sneet | ι Οι ι | | | | | | |
|---------------|----------------------------------|------------------------------------|--|-------------------------|--|--|--------------|
| ONFORM | HATION DISCLOSURE | ATTY. DOCKET NO. | | SERIAL NO. | | <u> </u> | |
| • | 74 | 121-175 | | 09/376,487 | | • | |
| JAH 2 & 200 | بع در تع | APPLICANT | | 02/3/0,40/ | | | |
| 3,7 | A C | MISHRA et al | | | | | |
| AN TE TRAIN | everal sheets if necessary) | FILING DATE | | GROUP | | | |
| THE | , | August 18, 199 | 00 | 1617 | | | |
| | | | NT DOCUMENTS | 1017 | | | |
| EXAMINER | | | | | | FILING | DATE |
| INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | IF APPRO | OPRIATI |
| | 5,478,860 | 12/1995 | Wheeler et al Carlsson et al | | - | | |
| | 5,688,528 | 2/2000 | George | | | | |
| | 6,028,108 6,140,373 | 10/2000 | May et al | - | | | |
| | 6,140,374 | 10/2000 | May et al | | | | , |
| | 6,147,122 | 11/2000 | Mirejovsky et al | | - | | |
| | 6,150,423 | 11/2000 | Carpenter | | | | · |
| | 6,177,477 | 1/2001 | George et al | | | | |
| | | | | | 1 | | |
| | | | | | | | ****** |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | <u> </u> | |
| | <u> </u> | | | | | ļ | |
| | | | | | | | |
| } | | | | | | | |
| ii | | EODEIGN DA | TENT DOCUMENTS | <u></u> | <u> </u> | L | |
| | | FOREIGN PA | TENT DOCUMENTS | | | TRANSI | LATION |
| | DOCUMENT | DATE | COUNTRY | CLASS | SUBCLASS | YES | NO |
| | WO 00/59471 | 10/2000 | WIPO | | | | |
| | WO 00/59472 | 10/2000 | WIPO | | | | |
| | WO 00/78301 | 12/2000 | WIPO | | <u> </u> | ļ | |
| _ | WO 97/10814 | 3/1997 | WIPO | | | <u> </u> | <u> </u> |
| | WO 98/53805 | 3/1998 | WIPOW | | <u> </u> | ļ | |
| | | <u> </u> | | | | | <u> </u> |
| - | | | | | 1 | | |
| | OTHER DOC | LIMENTS (including | Author, Title, Date, Per | tinont nagos | oto \ | <u>. </u> | · |
| | OTHER DOC | JOWENTS (Including | Addition, Title, Date, Per | unent pages, | etc.) | | |
| | | | ······································ | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | · | | | | | | |
| | | ** | | | | | |
| Examiner | | | Date Considered | | | | |
| | reference considered whether | or not citation is in conformaces: | with MPEP 609; Draw line through | citation if not in conf | ormance and not | considered | Include |
| | ith next communication to applic | | Ci Coo, Dian inic unough | | | | |
| | | | | | Form PTO-FB | -A820 (Also | PTO-14 |

INFORMATION DISCLOSTATEMENT BY APPLI

(Use as many sheets as necessary)

Sheet 12 of

| | Complete if Kn wn | |
|------------------------|--------------------|--|
| Application Number | 09/376,487 | |
| Filing Date | 8/18/99 | |
| First Named Inventor | Awadhesh K. Mishra | |
| Group Art Unit | 1617 | |
| Examiner Name | E. Webman | |
| Attorney Docket Number | 402090/SKYEPHARMA | |

| | | | | J.S. PATENT DOCUMENTS | | |
|-------------------|----------|---------------------------------|--------------|-------------------------------|------------------------|------------------------------|
| | | U.S. Patent Docum | | | 5 | |
| Examiner Initials | Doc. No. | Application or Patent Number | Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriat |
| | 1 | 2803582 | | Cherney | 8/20/1957 | |
| | 2 | 3137631 | | Soloway | 6/16/1964 | |
| | 3 | 3216897 | | Krantz et al. | 11/9/1965 | |
| | 4 | 3274063 | | Nieper et al. | 9/20/1966 | |
| | 5 | 3440318 | | Polin | 4/22/1969 | |
| | 6 | 3594476 | | Merrill | 7/20/1971 | |
| | 7 | 3715432 | | Merrill | 2/6/1973 | |
| | 8 | 3755557 | | Jacobs | 8/28/1973 | |
| | 9 | 3776857 | | Lindner | 12/4/1973 | |
| | 10 | 3794476 | | Michalik et al. | 2/26/1974 | |
| | 11 | 3937668 | | Zolle | 2/10/1976 | |
| | 12 | 3960757 | | Morishita et al. | 6/1/1976 | |
| | 13 | 3965255 | | Bloch et al. | 6/22/1976 | |
| | 14 | 4016100 | | Suzuki et al. | 4/5/1977 | |
| | 15 | 4053585 | | Allison et al. | 10/11/1977 | • |
| | 16 | 4073943 | | Wretlind et al. | 2/14/1978 | |
| | 17 | 4078052 | | Papahadjopoulos | 3/7/1978 | |
| | , 18 | 4089801 | | Schneider | 5/16/1978 | |
| | 19 | 4102806 | | Kondo et al. | 7/25/1978 | |
| | 20 | 4107288 | | Oppenheim et al. | 8/15/1978 | , |
| | 21 | 4133874 | <u> </u> | Miller et al. | 1/9/1979 | |
| | 22 | 4145410 | | Sears | 3/20/1979 | |
| | 23 | 4147767 | | Yapel, Jr. | 4/3/1979 | |
| | 24 | 4168308 | | Wretlind et al. | 9/18/1979 | |
| | 25 | 4186183 | | Steck et al. | 1/29/1980 | |
| _, | 26 | 4219548 | | Reller | 8/26/1980 | |
| | 27 | 4235871 | <u> </u> | Papahadjopoulos et al. | 11/25/1980 | |
| | 28 | 4241046 | | Papahadjopoulos et al. | 12/23/1980 | |
| | 29 | 4271196 | 1 | Schmidt | 6/2/1981 | |
| | 30 | 4298594 | | Sears et al. | 11/3/1981 | |
| | 31 | 4302459 | | Steck et al. | 11/24/1981 | |
| | 32 | 4308166 | | Marchetti et al. | 12/29/1981 | |
| | 33. | 4309421 | + | Ghyczy et al. | 1/5/1982 | |
| | 34 | 4316884 | | Alam et al. | 2/23/1982 | |
| | 35 | 4320121 | | Sears | 3/16/1982 | |
| | 36 | 4325871 | _ | Sasaki et al. | 4/20/1982 | |
| | 37 | 4328222 | | Schmidt | 5/4/1982 | |
| | 38 | 4329332 | + | Couvreur et al. | 5/11/1982 | |

| Examiner Signature | Date Considered |
|--------------------|-----------------|
| | |

A concis statement of relevance is being submitted in li u of a translation. 37 CFR 1.98(a)(3).

An English-language equival nt/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of rel vance found by the foreign office is being submitted in lieu of a concise explanation of relevance und r 37 CFR 1.98(a)(3).

INFORMATION DESCLOSISTATEMENT BY APPLIES.

(Use as many sheets as necessary)

Sheet 12 2 of

| | C mplete if Known | |
|------------------------|--------------------|--|
| Application Number | 09/376,487 | |
| Filing Date | 8/18/99 | |
| First Named Inventor | Awadhesh K. Mishra | |
| Group Art Unit | 1617 | |
| Examiner Name | E. Webman | |
| Attorney Docket Number | 402090/SKYEPHARMA | |

| | _ | U.S. Patent Docum | ent | | | |
|-------------------|----------|---------------------------------|--|-------------------------------|------------------------|-------------------------------|
| Examiner Initials | Doc. No. | Application or Patent Number | Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriate |
| | 39 | 4331654 | | Morris | 5/25/1982 | |
| | 40 | 4332795 | | Ghyczy et al. | 6/1/1982 | |
| | 41 | 4332796 | | Los | 6/1/1982 | |
| | 42 | 4340594 | | Mizushima et al. | 7/20/1982 | |
| | 43 | 4345588 | | Widder et al. | 8/24/1982 | |
| | 44 | 4351831 | | Growdon et al. | 9/28/1982 | |
| | 45 | 4356167 | | Kelly | 10/26/1982 | |
| | 46 | 4369182 | | Ghyczy et al. | 1/18/1983 | |
| | 47 | 4378354 | | Ghyczy et al. | 3/29/1983 | |
| | 48 | 4394182 | | Maddox, III | 7/19/1983 | |
| | 49 | 4394372 | | Taylor | 7/19/1983 | |
| | 50 | 4397372 | | DeKraker | 8/9/1983 | |
| | 51 | 4397846 | | Weiner et al. | 8/9/1983 | |
| | 52 | 4411894 | | Schrank et al. | 10/25/1983 | |
| | 53 | 4411933 | | Samejima et al. | 10/25/1983 | |
| | 54 | 4421747 | | Ghyczy et al. | 12/20/1983 | |
| | 55 | 4427649 | | Dingle et al. | 1/24/1984 | |
| | 56 | 4448765 | | Ash et al. | 5/15/1984 | |
| | 57 | 4452817 | | Glen et al. | 6/5/1984 | |
| | | 4474753 | | Haslam et al. | 10/2/1984 | |
| | 58 | | | Augart | 1/20/1984 | |
| | 59 | 4483847 | | Mezei et al. | 11/27/1984 | |
| | 60 | 4485054 | | Mosier | 1/8/1985 | |
| | 61 | 4492720 | + | | 5/7/1985 | |
| | 62 | 4515736 - | | Deamer | 6/11/1985 | |
| | 63 | 4522803. | | Lenk et al. Hunt et al. | 7/16/1985 | |
| | 64 | 4529561 | | | 7/30/1985 | |
| | 65 | 4532089 | | MacDonald | | |
| | - 66 | 4588578 | | Fountain et al. | 5/13/1986 | |
| | 67 | 4610868 | | Fountain et al. | 9/9/1986 | |
| | 68 | 4613505 | | Mizushima et al. | 9/23/1986 | |
| | 69 | 4614702 | | Sawada et al. | 9/30/1986 | |
| | 70 | 4622219 | | Haynes | 11/11/1986 | |
| | 71 | 4675236 | | . Ohkawara et al. | 6/23/1987 | |
| | 72 | 4687762 | | Fukushima et al. | 8/18/1987 | |

| 1 | Examiner Signature | Date Considered |
|---|--------------------|-----------------|
| | | |

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

⁺ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

INFORMATION DISCLOSISTATEMENT BY ARREST

(Use as many sheets as necessary)

Sheet 12 of

| | Complete if Known | |
|------------------------|--------------------|--|
| Application Number | 09/376,487 | |
| Filing Date | 8/18/99 | |
| First Named Inventor | Awadhesh K. Mishra | |
| Group Art Unit | 1617 | |
| Examiner Name | E. Webman | |
| Attorney Docket Number | 402090/SKYEPHARMA | |

| | | | Ü | I.S. PATENT DOCUMENTS | | |
|---------------------------------------|----------|--|--|-------------------------------|------------------------|---------------------------------------|
| Examiner Initials | Doc. No. | U.S. Patent Docum Application or Patent Number | Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriate |
| | 73 | 4711902 | | Serno | 12/8/1987 | |
| | 74 | 4719239 | | Muller et al. | 1/12/1988 | |
| | 75 | 4725442 | | Haynes | 2/16/1988 | |
| | 76 | 4756910 | | Yagi et al. | 7/12/1988 | |
| | 77 | 4761228 | † | Weisenbarger et al. | 8/2/1988 | |
| - | 78 | 4762720 | T | Jizomoto | 8/9/1988 | |
| | 79 | 4766046 | | Abra et al. | 8/23/1988 | |
| | 80 | 4776991 | | Farmer et al. | 10/11/1988 | |
| | 81 | 4798846 | | Glen et al. | 1/17/1989 | |
| | 82 | 4798860 | | Parr | 1/17/1989 | |
| | 83 | 4800079 | | Boyer | 1/24/1989 | · |
| | 84 | 4801455 | 1 | List et al. | 1/31/1989 | |
| | 85 | 4803070 | | Cantrell et al. | 2/7/1989 | |
| | 86 | 4806350 | | Gerber | 2/21/1989 | |
| · · · · · · · · · · · · · · · · · · · | 87 | 4806352 | · | Cantrell | 2/21/1989 | |
| | 88 | 4826687 | † | Nerome et al. | 5/2/1989 | |
| | 89 | 4839111 | | Huang | 6/13/1989 | |
| | 90 | 4863737 | | Stanley et al. | 9/5/1989 | |
| | 91 | 4863740 | | Kissel et al. | 9/5/1989 | |
| | 92 | 4895726 | 1 | Curtet et al. | 1/23/1990 | |
| | 93 | 4937078 | | Mezei et al. | 6/26/1990 | |
| | 94 | 4961890 | | Boyer | 10/9/1990 | |
| | 95 | 4963362 | | Rahman et al. | 10/16/1990 | |
| | 96 | 4963367 | | Ecanow | 10/16/1990 | |
| | 97 | 4973465 | | Baurain et al. | 11/27/1990 | |
| | 98 | 5004612 ⁻ | : | Kim et al. | 4/2/1991 | |
| | 99 . | 5023087 | + | Yau-Young | 6/11/1991 | |
| | 100 | 5028600 | | Jeppsson | 7/2/1991 | |
| | 101 | 5030453 | <u> </u> . | Lenk et al. | 7/9/1991 | |
| | 102 | 5049388 | | Knight et al. | 9/17/1991 | · · · · · · · · · · · · · · · · · · · |
| | 103 | 5091187 | | Haynes | 2/25/1992 | |
| | 103 | 5091188 | - | Haynes | 2/25/1992 | |
| | 105 | 5098606 | + | Nakajima et al. | 3/24/1992 | |

| Examin r Signature | Date Considered | · . |
|--------------------|-----------------|-----|
| | | |

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
 An English-language equivalent/patent, or an English-languag abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degre of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

| Please type a plus sign (+) i | inside this box | ł |
|-------------------------------|-----------------|---|
|-------------------------------|-----------------|---|

JAN 2 4 2003

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Filing Date First Named Inventor Complete if Known 09/376,487

8/18/99

Awadhesh K. Mishra 1617

Group Art Unit

Application Number

E. Webman

Examiner Name

(Use as many sheets as necessary) of

Sheet

Attorney Docket Number

402090/SKYEPHARMA

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|----------|--|--|-------------------------------|------------------------|-------------------------------|
| Examiner Initials | Doc. No. | U.S. Patent Docum Application or Patent Number | Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriate |
| | 106 | 5100591 | | Leclef et al. | 3/31/1992 | • |
| | 107 | 5118493 | | Kelley et al. | 6/2/1992 | |
| | 108 | 5128147 | | Leveen et al. | 7/7/1992 | |
| | 109 | 5132114 | | Stanley et al. | 7/21/1992 | |
| | 110 | 5133965 | | Fountain | 7/28/1992 | |
| | 111 | 5145684 | | Liversidge et al. | 9/8/1992 | <u> </u> |
| | 112 | 5147884 | | Diehl et al. | 9/15/1992 | |
| | 113 | 5152923 | | Weder et al. | 10/6/1992 | |
| | 114 | 5167950 | | Lins | 12/1/1992 | |
| - | 115 | 5179079 | 1 | Hansen et al. | 1/12/1993 | |
| | 116 | 5188837 | | Domb | 2/23/1993 | |
| | 117 | 5217707 | | Szabo et al. | 6/8/1993 | |
| | 118 | 5227165 | | Domb et al. | 7/13/1993 | |
| | 119 | 5234634 | | Janoff et al. | 8/10/1993 | • |
| | 120 | 5234767 | | Wallach | 8/10/1993 | |
| - | 121 | 5244925 | | Wretlind et al. | 9/14/1993 | |
| | 122 | 5246707 | | Haynes | 9/21/1993 | |
| | 123 | 5256422 | | Albert et al. | 10/26/1993 | |
| | 124 | 5256641 | | Yatvin et al. | 10/26/1993 | |
| | 125 | 5264207 | | Bommelaer et al. | 11/23/1993 | |
| | 126 | 5269979 | <u> </u> | Fountain | 12/14/1993 | |
| | 127 | 5288497 | | Stanley et al. | 2/22/1994 | |
| | 128 | 5288498 | | Stanley et al. | 2/22/1994 | |
| | 129 | 5294604 | | Nussenblatt et al. | 3/15/1994 | |
| | 130 | 5298262 | 1 | Na et al. | 3/29/1994 | |
| | 131 | 5302401 | | Liversidge et al. | 4/12/1994 | |
| | 132 | 5308874 ~ | | Sanchez et al. | 5/3/1994 | |
| | 133. | 5314915 | | Rencher | 5/24/1994 | |
| | 134 | 5326552 | | Na et al. | 7/5/1994 | |
| | 135 | 5332576 | | Mantelle | 7/26/1994 | |
| | 136 | 5336507 | 1 | Na et al. | 8/9/1994 | |
| | 137 | 5338761 | + | Nakajima et al. | 8/16/1994 | |

| Examiner Signature | Date Considered |
|--------------------|-----------------|
| <u> </u> | |

^{*} A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

INFORMATION DISCLOS STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 12 of

| J | | |
|---|------------------------|--------------------|
| | | Complete if Known |
| | Application Number | 09/376,487 |
| | Filing Date | 8/18/99 |
| | First Named Inventor | Awadhesh K. Mishra |
| | Group Art Unit | 1617 |
| | Examiner Name | E. Webman |
| | Attorney Docket Number | 402090/SKYEPHARMA |

| | | | Ţ | J.S. PATENT DOCUMENTS | | |
|----------------------|----------|--|----------------------|-------------------------------|---------------------|-------------------------------|
| Examiner Initials | Doc. No. | U.S. Patent Docur Application or Patent Number | ment Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriate |
| | 138 | 5340588 | | Domb | 8/23/1994 | |
| | 139 | 5346702 | | Na et al. | 9/13/1994 | |
| | 140 | 5352459 | | Hollister et al. | 10/4/1994 | |
| | 141 | 5364633 | | Hill et al. | 11/15/1994 | |
| | 142 | 5376646 | | Pittrof et al. | 12/27/1994 | |
| | 143 | 5378451 | | Gorman et al. | 1/3/1995 | |
| | 144 | 5389377 | | Chagnon et al. | 2/14/1995 | |
| | 145 | 5399363 | | Liversidge et al. | 3/21/1995 | |
| | 146 | 5407609 | | Tice et al. | 4/18/1995 | |
| | 147 | 5409698 | | Anderson et al. | 4/25/1995 | |
| | 148 | 5429824 | | June | 7/4/1995 | |
| | 149 | 5446070 | | Mantelle | 8/29/1995 | |
| | 150 | 5447710 | | Na et al. | 9/5/1995 | |
| | 151 | 5451408 | | Mezei et al. | 9/19/95 | |
| | 152 | 5461080 | | Sanchez et al. | 10/24/1995 | |
| | 153 | 5496537 | | Henry | 3/5/1996 | |
| | 154 | 5496811 | | Aviv et al. | 3/5/1996 | |
| | 155 | 5496818 | | Schaupp et al. | 3/5/1996 | |
| | 156 | 5498420 | | Mentrup Edgar et al. | 3/12/1996 | |
| | 157 | 5498421 | | Grinstaff et al. | 3/12/1996 | |
| | 158 | 5508275 | | Weithmann et al. | 4/16/1996 | |
| | 159 | 5510118 | | Bosch et al. | 4/23/1996 | |
| | 160 | 5518187 | | Bruno et al. | 5/21/1996 | |
| | 161 | 5518730 | | Fuisz | 5/21/1996 | |
| | 162 | 5527537 | | Dietl | 6/18/1996 | |
| | 163 | 5534270 | | De Castro . | 7/9/1996 | |
| | 164 | 5536413 | | Bormann et al. | 7/16/1996 | |
| | 165- | 5545628 | | Deboeck et al. | 8/13/1996 | |
| | 166 | 5556580 | | Suddith | 9/17/1996 | |

| Examiner Signature | Date Considered |
|--------------------|-----------------|
| § | |

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

⁺ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

INFORMATION DISCLOSURE STATEMENT BY ARBUTEANT

(Use as many sheets as necessary)

Sheet of

| | Complet if Kn wn |
|------------------------|--------------------|
| Application Number | 09/376,487 |
| Filing Date | 8/18/99 |
| First Named Inventor | Awadhesh K. Mishra |
| Group Art Unit | 1617 |
| Examiner Name | E. Webman |
| Attorney Docket Number | 402090/SKYEPHARMA |

| | | | | J.S. PATENT DOCUMENTS | | |
|----------------------|-------------|--|----------------------|-------------------------------|------------------------|-------------------------------|
| Examiner Initials | Doc. No. | U.S. Patent Docur Application or Patent Number | ment Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriate |
| | 167 | 5560931 | | Eickhoff et al. | 10/1/1996 | |
| | 168 | 5569464 | | Endo et al. | 10/29/1996 | |
| | 169 | 5571536 | | Eickhoff et al. | 11/5/1996 | |
| | 170 | 5576012 | | Bauer et al. | 11/19/1996 | |
| | 171 . | 5576016 | | Amselem et al. | 11/19/1996 | |
| | 172 | 5589455 | | Woo | 12/31/1996 | |
| | 173 | 5589598 | | Paiocchi | 12/31/1996 | |
| | 174 | 5591311 | | Ramachandran | 1/7/1997 | |
| : | 175 | 5603951 | | Woo | 2/18/1997 | |
| | 176 | 5607694 | | Marx | 3/4/1997 | |
| | 177 | 5618522 | | Kaleta et al. | 4/8/1997 | |
| | 178 | 5618563 | | Berde et al. | 4/8/1997 | |
| | 179 | 5626869 | | Nyqvist et al. | 5/6/1997 | |
| | 180 | 5631019 | · | Marx | 5/20/1997 | , |
| | 181 | 5635203 | | Gale et al. | 6/3/1997 | |
| | 182 | 5635205 | | Nyqvist et al. | 6/3/1997 | |
| | 183 | 5635536 | | Lyons | 6/3/1997 | |
| | 184 | 5635540 | | Edlich et al. | 6/3/1997 | |
| | 185 | 5639474 | | Woo | 6/17/1997 | |
| | 186 | 5641508 | | Li et al. | 6/24/1997 | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | - | | | | |
| | | | + | | | |
| | | | | | | |

| Examiner Signature | ž . | Date Considered | |
|--------------------|-----|-----------------|--|
| | | | |

^{*} A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concis explanation of relevance under 37 CFR 1.98(a)(3).



INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet of 12

| | C mplete if Known |
|------------------------|--------------------|
| Application Number | 09/376,487 |
| Filing Date | 8/18/99 |
| First Named Inventor | Awadhesh K. Mishra |
| Group Art Unit | 1617 |
| Examiner Name | E. Webman |
| Attorney Docket Number | 402090/SKYEPHARMA |

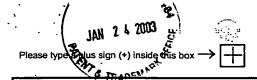
| | I | U.S. Patent Docur | | J.S. PATENT DOCUMENTS | | |
|----------------------|----------|---------------------------------|--------------|-------------------------------|------------------------|-------------------------------|
| Examiner Initials | Doc. No. | Application or Patent Number | Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriate |
| | 187 | 5645856 | | Lacy et al. | 7/8/1997 | |
| | 188 | 5648375 | | Abraham | 7/15/1997 | |
| | 189 | 5651982 | | Marx | 7/29/1997 | |
| | 190 | 5651991 | | Sugiyama et al. | 7/29/1997 | |
| | 191 | 5656280 | | Herb et al. | 8/12/1997 | |
| | 192 | 5656286 | | Miranda et al. | 8/12/1997 | |
| | 193 | 5656289 | | Cho et al. | 8/12/1997 | |
| | 194 | 5658583 | | Zhang et al. | 8/19/1997 | |
| | 195 | 5660837 | | Lundquist | 8/26/1997 | |
| | 196 | 5660854 | | Haynes et al. | 8/26/1997 | |
| | 197 | 5660858 | | Parikh et al. | 8/26/1997 | |
| | 198 | 5662932 | | Amselem et al. | 9/2/1997 | |
| | 199 | 5665380 | | Wallach et al. | 9/9/1997 | |
| | 200 | 5665700 | | Cho et al. | 9/9/1997 | |
| | 201 | 5667809 | | Trevino et al. | 9/16/1997 | |
| | 202 | 5677341 | | Lyons | 10/14/1997 | |
| | 203 | 5686102 | | Gross et al. | 11/11/1997 | |
| | 204 | 5693337 | | Suzuki et al. | 12/2/1997 | |
| | 205 | 5700482 | | Frederiksen et al. | 12/23/1997 | |
| | 206 | 5705039 | | Clarke et al. | 1/6/1998 | - |
| | 207 | 5719197 | | Kanios et al. | 2/17/1998 | |
| | 208 | 5731355 | | Jones et al. | 3/24/1998 | |
| | 209 | 5731356 | | Jones et al. | 3/24/1998 | <u> </u> |
| | 210 | 5733572 | | Unger et al. | 3/31/1998 | |
| | 211 | 5747060 | | Sackler et al. | 5/5/1998 | |
| | 212 | 5750137 - | | Taskovich et al. | 5/12/1998 | |
| | 213 | 5750142 | | Friedman et al. | 5/12/1998 | |
| _ | 214 | 5753258 | | Schreier et al. | 5/19/1998 | |
| | 215 | 5756120 | | Hersch et al. | 5/26/1998 | |
| | 216 | 5756121 | | Bracken | 5/26/1998 | |
| | 217 | 5759571 | 1 | Hersch et al. | 6/2/1998 | |
| | 218 | 5766625 | | Schreier et al. | 6/16/1998 | |
| | 219 | 5766627 | | Sankaram et al. | 6/16/1998 | |
| | 220 | 5770222 | | Unger et al. | 6/23/1998 | |
| | 221 | 5773026 | | Schlipalius | 6/30/1998 | |

| | · _ | | |
|--------------------|-----|-----------------|--|
| Examin r Signature | | Date Considered | |
| _ | | 1 | |

A concis statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

A concis statement of relevance is being submitted in field of a datistation. 37 GFR 1.30(a)(3).

An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 GFR 1.98(a)(3).



INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)
Sheet 8 of

| | Complete if Known | |
|------------------------|--------------------|--|
| Application Number | 09/376,487 | |
| Filing Date | 8/18/99 | |
| First Named Inventor | Awadhesh K. Mishra | |
| Group Art Unit | 1617 | |
| Examiner Name | E. Webman | |
| Attorney Docket Number | 402090/SKYEPHARMA | |

| | | | | J.S. PATENT DOCUMENTS | | |
|--|------|----------------------|--|------------------------|-------------------------------|---------------------------------------|
| Examiner Initials U.S. Patent Document Application or Patent Number | | Ment Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriate | |
| IIIIIIIII | 222 | 5773106 | Code | deGroot et al. | 6/30/1998 | Арргорнате |
| | 223 | 5776488 | | Mori et al. | 7/7/1998 | · · · · · · · · · · · · · · · · · · · |
| | 224 | 5776495 | | Duclos et al. | 7/7/1998 | |
| | 225 | 5780045 | + | McQuinn et al. | 7/14/1998 | • |
| | 226 | 5785976 | + | Westesen et al. | 7/28/1998 | |
| | 227 | 5785989 | | Stanley et al. | 7/28/1998 | - |
| | 228 | 5785991 | + | Burkoth et al. | 7/28/1998 | |
| | 229 | 5789411 | + | Gooberman et al. | 8/4/1998 | |
| | 230 | 5807316 | | Teeple, Jr. | 9/15/1998 | |
| | 231 | 5807534 | | Pomato et al. | 9/15/1998 | |
| | 232 | 5807572 | 1 | Kim et al. | 9/15/1998 | · · · · · · · · · · · · · · · · · · · |
| | 232 | 5807573 | + | Ljusberg-Wahren et al. | 9/15/1998 | |
| | 234 | 5827533 | | Needham | 10/27/1998 | |
| | 235 | 5827534 | | Fasano | 10/27/1998 | |
| | 236 | 5827822 | | Floc'h et al. | 10/27/1998 | |
| | 237 | 5843465 | | Lundquist | 12/1/1998 | |
| | 238 | 5843468 | | Burkoth et al. | 12/1/1998 | |
| | 239 | 5843474 | | Williams | 12/1/1998 | |
| | 240 | 5853755 | | Foldvari | 12/29/1998 | |
| | 241 | 5855908 | | Stanley et al. | 1/5/1999 | |
| | 242 | 5858398 | | Cho | 1/12/1999 | 7. |
| | 243 | 5858401 | 1 | Bhalani et al. | 1/12/1999 | |
| | 244 | 5858410 | | Muller et al. | 1/12/1999 | |
| | 245 | 5882676 ⁻ | <u> </u> | Lee et al. | 3/16/1999 | |
| | 246 | 5885172 | - | Hebert et al. | 3/23/1999 | |
| | 247 | 5885597 | | Botknecht et al. | 3/23/1999 | |
| | 248 | 5908619 | 1 | Scholz | 6/1/1999 | |
| | 249 | 5908825 | | Fasano et al. | 6/1/1999 | |
| | 250 | 5908869 | | Jones et al. | 6/1/1999 | |
| | 251 | 5912007 | | Pan et al. | 6/15/1999 | |
| | 252 | 5912271 | | Brodin et al. | 6/15/1999 | |
| | 253 | 5916596 | | Desai et al. | 6/29/1999 | |
| | 254 | 5922340 | | Berde et al. | 7/13/1999 | |
| | | - | + | | | |

Examiner Signature Date Considered

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

⁺ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

| Please | type a | plus sign | (+) | inside | this | bo |
|--------|--------|-----------|-----|--------|------|----|
|--------|--------|-----------|-----|--------|------|----|

JAN 2 4 2003

INFORMATION DISCLOSURE STATEMENT BY APPEICANT

(Use as many sheets as necessary)

Sheet of

| Complete if Known | | | | |
|------------------------|--------------------|--|--|--|
| Application Number | 09/376,487 | | | |
| Filing Date . | 8/18/99 | | | |
| First Named Inventor | Awadhesh K. Mishra | | | |
| Group Art Unit | 1617 | | | |
| Examiner Name | E. Webman | | | |
| Attorney Docket Number | 402090/SKYEPHARMA | | | |

| | | | L | J.S. PATENT DOCUMENTS | | |
|----------------------|----------|--|--------------|-------------------------------|------------------------|------------------------------|
| Examiner Initials | Doc. No. | U.S. Patent Docur Application or Patent Number | Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Dat If Appropriate |
| | 255 | 5922355 | | Parikh et al. | 7/13/1999 | |
| | 256 | 5922705 | | Simon | 7/13/1999 | |
| | 257 | 5925014 | | Teeple Jr. | 7/20/1999 | |
| | 258 | 5932243 | | Fricker et al. | 8/3/1999 | |
| | . 259 | 5942497 | | Fukunaga et al. | 8/24/1999 | |
| | 260 | 5945510 | | Fasano | 8/31/1999 | |
| | 261 | 5958379 | T | Regenold et al. | 9/28/1999 | |
| | 262 | 5958449 | | Hersch et al. | 9/28/1999 | |
| | 263 | 5962536 | | Komer | 10/5/1999 | |
| | 264 | 5972366 | | Haynes et al. | 10/26/1999 | |
| | 265 | 5972938 | | Rupniak et al. | 10/26/1999 | |
| | 266 | 5980936 | | Krafft et al. | 11/9/1999 | · · · · - |
| | 267 | 5990176 | | Bieniarz et al. | 11/23/1999 | |
| | 268 | 5993850 | | Sankaram et al. | 11/30/1999 | |
| | 269 | 5994318 | | Gould-Fogerite et al. | 11/30/1999 | |
| | 270 | 6004566 | | Friedman et al. | 12/21/1999 | |
| | 271 | 6004962 | | Gooberman | 12/21/1999 | |
| | 272 | 6011067 | | Hersh | 1/4/2000 | |
| | 273 | 6013665 | | DeMichele et al. | 1/11/2000 | |
| | 274 | 6017513 | | Betbeder et al. | 1/25/2000 | |
| | 275 | 6019997 | | Scholz et al. | 2/1/2000 | |
| • . | 276 | 6022547 | | Herb et al. | 2/8/2000 | |
| , | 277 | 6024976 | | Miranda et al. | 2/15/2000 | |
| | 278 | 6025362 | | Fukunaga et al. | 2/15/2000 | |
| | 279 | 6028066 | | Unger | 2/22/2000 | |
| | | - | | | | |
| | - | | | | | |

| Examiner Signature | Date Considered | |
|--------------------|-----------------|--|
| • | l | |

<sup>A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise</sup> xplanation of relevance under 37 CFR 1.98(a)(3).

JAN 2 4 2003

12

Substitute for form 1449A/B/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary) 10 of

| | Complet if Known |
|------------------------|--------------------|
| Application Number | 09/376,487 |
| Filing Date | 8/18/99 |
| First Named Inventor | Awadhesh K. Mishra |
| Group Art Unit | 1617 |
| Examiner Name | E. Webman |
| Attorney Docket Number | 402090/SKYEPHARMA |

| | | | ι | J.S. PATENT DOCUMENTS | | |
|----------------------|----------|--|--|-------------------------------|---------------------|----------------------------|
| Examiner Initials | Doc. No. | U.S. Patent Docun Application or Patent Number | Nent Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriate |
| | 280 | 6031007 | | Brodin et al. | 2/29/2000 | |
| | 281 | 6046163 | | Stuchlik et al. | 4/4/2000 | |
| | 282 | 6046187 | | Berde et al. | 4/4/2000 | |
| • | 283 | 6054421 | | Lyons et al. | 4/25/2000 | |
| | 284 | 6057289 | | Mulye | 5/2/2000 | - |
| | 285 | 6063762 | | Hong et al. | 5/16/2000 | |
| | 286 | 6071534 | 1 | Kim et al. | 6/6/2000 | |
| | 287 | 6071927 | | Baker et al. | 6/6/2000 | |
| | 288 | 6071928 | | Curtis et al. | 6/6/2000 | |
| | 289 | 6071933 | | Joo et al. | 6/6/2000 | |
| | 290 | 6071974 | | Patel et al. | 6/6/2000 | |
| | 291 | 6075059 | | Reader | 6/13/2000 | |
| | 292 | 6079416 | | Williams | 6/27/2000 | |
| | 293 | 6086376 | | Moussa et al. | 7/11/2000 | |
| | 294 | 6086911 | | Godbey | 7/11/2000 | |
| | 295 | 6096338 | | Lacy et al. | 8/1/2000 | |
| | 296 | 6103269 | | Wunderlich et al. | 8/15/2000 | |
| | 297 | 6106848 | | Preuilh et al. | 8/22/2000 | |
| | 298 | 6106858 | | Ye et al. | 8/22/2000 | |
| | 299 | 6113921 | | Friedman et al. | 9/5/2000 | |
| | 300 | 6117066 | | Abrams et al. | 9/12/2000 | |
| | 301 | 6120797 | | Meers et al. | 9/19/2000 | |
| | 302 | 6121261 | | Glatt et al. | 9/19/2000 | |
| | 303 | 6123923 | | Unger et al. | 9/26/2000 | |
| | 304 | 6132766 | | Sankaram et al. | 10/17/2000 | |
| | 305 | 6153217 | | Jin et al. | 11/28/2000 | |
| | 306 | 6160007 | | DeMichele et al. | 12/12/2000 | |
| | <u> </u> | · | | | | |

| Examin r Signature | Date Considered |
|--------------------|-----------------|
| | |

^{*} A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

| | Complete if Kn wn | |
|------------------------|--------------------|--|
| Application Number | 09/376,487 | |
| Filing Date | 8/18/99 | |
| First Named Inventor | Awadhesh K. Mishra | |
| Group Art Unit | 1617 | |
| Examiner Name | E. Webman | |
| Attorney Docket Number | 402090/SKYEPHARMA | |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|----------|---------------------------------|--------------|-------------------------------|------------------------|------------------------------|
| | | U.S. Patent Docum | nent | | | |
| Examiner Initials | Doc. No. | Application or Patent Number | Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriat |
| | 307 | 6180136 | | Larson et al. | 1/30/2001 | |
| | 308 | 6190894 | | Thornfeldt et al. | 2/20/2001 | |
| | 309 | 6197323 | | Georgieff | 3/6/2001 | |
| | 310 | 6204257 | | Stella et al. | 3/20/2001 | |
| , | 311 | 6217886 | | Önyüksel et al. | 4/17/2001 | |
| | 312 | 6221383 | | Miranda et al. | 4/24/2001 | |
| | 313 | 6228399 | | Parikh et al. | 5/8/2001 | |
| | 314 | 6232311 | | Rupniak et al. | 5/15/2001 | |
| | 315 | 6242446 | | Glatt et al. | 6/5/2001 | |
| | 316 | 6254853 | | Hendler et al. | 7/3/2001 | |
| | 317 | 6261537 | | Klaveness et al. | 7/17/2001 | |
| | 318 | 6264917 | | Klaveness et al. | 7/24/2001 | |
| | 319 | 6264981 | | Zhang et al. | 7/24/2001 | |
| | 320 | 6267985 | | Chen et al. | 7/31/2001 | |
| | 321 | 6274633 | | Franks et al. | 8/14/2001 | |
| | 322 | 6281175 | | Lyons et al. | 8/28/2001 | |
| | 323 | 6281242 | | Regan et al. | 8/28/2001 | |
| | 324 | 6288040 | | Müller et al. | 9/11/2001 | . - |
| | 325 | 6288127 | | Bieniarz et al. | 9/11/2001 | |
| | 326 | 6294191 | | Meers et al. | 9/25/2001 | |
| | 327 | 6294192 | | Patel et al. | 9/25/2001 | |
| | 328 | 6297985 | | Kang | 10/2/2001 | |
| <u> </u> | 329 | 6309623 | | Weers et al. | 10/30/2001 | |
| | 330 | 6312715 | | Cantor et al. | 11/6/2001 | |
| | 331 | 6326406 | | DeTommaso | 12/4/2001 | |
| | 332 | 6328708 | | Georgieff . | 12/11/2001 | |
| | 333 | 6331289 ~ | | Klaveness et al. | 12/18/2001 | |
| | 334. | 6332138 ⁻ | | Hull et al. | 12/18/2001 | |
| | 335 | 6350480 | | Urnezis et al. | 2/26/2002 | |
| | 336 | 6362234 | | Hendler | 3/26/2002 | |
| | 337 | 6383471 | | Chen et al. | 5/7/2002 | |
| | 338 | 6391336 | | Royer | 5/21/2002 | |
| | 339 | 6391832 | | Lyons et al. | 5/21/2002 | |
| | 340 | 6399087 | | Zhang et al. | 6/4/2002 | |

| Examiner Signature | Date Considered |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
| • | |
| | |

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
 An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise xplanation of relevance under 37 CFR 1.98(a)(3).

| Substitute for form 1449A/B/PT | JAN 2 4 200 E |
|---------------------------------|---------------|
| Substitute for form 1449A/B/PTO | N DISCLOSURE |
| STATEMENT | BY APPEICANT |

Filing Date 8/18/99 First Named Inventor Awadhesh K. Mishra Group Art Unit 1617 E. Webman **Examiner Name** 402090/SKYEPHARMA Attomey Docket Number

Complet if Known

09/376,487

(Use as many sheets as necessary) 12 Sheet 12 of

| | | | Ū | J.S. PATENT DOCUMENTS | | |
|----------------------|--|---|--|-------------------------------|------------------------|---------------------------------------|
| Examiner Initials | Doc. No. | U.S. Patent Docume Application or Patent Number | ent Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriate |
| | 341 | 6410583 | | Labelle et al. | 6/25/2002 | |
| | 342 | 6423338 | | Larson et al. | 7/23/2002 | |
| | 343 | 2001/0007663 | | Von Corswant | 7/12/2001 | |
| | 344 | 2001/0046474 | | Weers et al. | 11/29/2001 | |
| | 345 | 2002/0006442A1 | | Mishra et al. | 1/17/2002 | |
| | 346 | Re. 32393 | <u> </u> | Wretlind et al. | 4/7/1987 | |
| | 347 | Re. 35338 | | Haynes | 9/24/1996 | |
| | | | | | | |
| | | · | | | | |
| | | _ | | | | |
| | · | | | | | |
| | | | | | | |
| | | | ļ | | | |
| | | | | · | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | <u> </u> | | <u> </u> | | | · · · · · · · · · · · · · · · · · · · |
| | | | | · | | |
| | | | | | | · · · · · · · · · · · · · · · · · · · |
| | | <u> </u> | | | | |
| | | <u> </u> | | | | |
| | | | | | | |

Application Number

| Examiner | I | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item | | |
|----------|----------|--|----------|------|
| Initials | Doc. No. | | | No*+ |
| _ | 348 | Letter regarding Collection/Validity Search of Amphiphilic Lipid-Coated Drug Formulations dated November 3, 2000 | | |
| | 349 | Letter regarding Collection/Validity Search of Surface-Stabilized Particles dated November 6, 2000. | | |
| | | | <u> </u> | |
| | | | ١, | |

| Examiner Signature | Date Considered | |
|--------------------|-----------------|---------|
| | | <u></u> |

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

An English-language equival nt/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet of

| Complete if Known | | | | | |
|------------------------|-----------------|--|--|--|--|
| Application Number | 9/376,487 | | | | |
| Filing Date | August 18, 1999 | | | | |
| First Named Inventor | MISHRA | | | | |
| Group Art Unit | 1617 | | | | |
| Examiner Name | E. Webman | | | | |
| Attorney Docket Number | 402090 | | | | |

| | | | U | .S. PATENT DOCUMENTS | | |
|----------------------|-------------|---------------------------------|--------------|-------------------------------|------------------------|-------------------------------|
| | | U.S. Patent Document | | | | |
| Examiner Initials | Doc. No. | Application or Patent Number | Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriate |
| | 1 | 4,056,635 | | Glen et al. | 11/1/1977 | |
| | 2 . | 4,280,996 | • | Okamoto et al. | 7/28/1981 | |
| | 3 | 4,309,421 | | Ghyczy et al. | 1/5/1982 | · |
| | 4 | 4,340,594 | | Mizushima et al. | 7/20/1982 | |
| | 5 | 4,687,762 | | Fukushima et al. | 8/18/1987 | |
| | 6 4,837,028 | | Allen | 6/6/1989 | | |
| | 7 | 4,880,634 | | Speiser | 11/14/1989 | |
| | 8. | 4,895,726 | | Curtet et al. | 1/23/1990 | 1 |
| | 9 | 5,023,087 | | Yau-Young | 6/11/1991 | |
| | 10 | 5,100,591 | | Leclef et al. | 3/31/1992 | |
| | - 11 | 5,320,906 | | Eley et al. | 6/14/1994 | |
| | 12 | 5,527,537 | | Dietl | 6/18/1996 | |
| | 13 | 5,827,520 | | de Salvert | 10/27/1998 | |
| ٠. | 14 | 5,827,536 | | Laruelle | 10/27/1998 | |
| | 15 | 5,880,148 | - | Edgar et al. | 3/9/1999 | |
| | 16 | | | | | |

| | | | | FOREIG | N PATENT DOCUMENTS | | | |
|-------------------|----------|-------------------------|---------------------------------|--------------|-------------------------------|------------------------|---------|------|
| | | Foreign Patent Document | | | | Trans | slation | |
| Examiner Initials | Doc. No. | Office · | Application or Patent Number | Kind Code | Name of Patentee or Applicant | Date of Publication | Yes | No*+ |
| | 17 | DE | 25 13 797 | | ICI Ltd. | 10/9/975 | | X+ |
| | 18 | DE | 29 38 807 | | Green Cross Corp. | 11/13/1980 | | X+ |
| | 19 | DE | 3421 468 | | Rentschler Arzenimittel | 12/19/1985 | | X+ |
| | 20 | EP | 052 322 | | Gersonde Klaus Prof Dr | 5/26/1982 | | X+ |
| - | 21 | EP | 057 829 | | Fullard | 8/18/1982 | | |
| | 22 | EP | 272 091 | ٠. | Vestar, Inc. | 6/22/1988 | | |
| | 23 | EP | 330 532 | | Fournier Innovation Synergie | 8/30/1989 | | X+. |
| | 24 | EP | 391 369 | | Yissum Research Dev. | 10/10/1990 | | Т |
| | 25 | EP | 418 153 | <u> </u> | Medgenix Group SA | 3/20/1991 | 1 | X+ |
| | 26 | EP | 456 670 | | Braun Melsungen AG | 11/21/1991 | 1 | X+ |
| | 27 | EP | 456 764 | | Braun Melsungen | 11/21/1991 | | X+ |
| | 28 | EP | 499 299 | | Sterling Winthrop Inc. | 8/19/1992 | T | |
| | 29 | EP | 535 567 | | Braun Melsungen AG | 4/7/1993 | T | X+ |
| | 30 | EP | 570 829 | | Hans | 11/24/1993 | 1 | X+ |
| | 31 | EP | 601 618 | | Sterling Winthrop Inc. | 6/15/1994 | 1 | 1 |
| | 32 | EP | 602 700 | | Sterling Winthrop Inc. | 6/22/1994 | | 1 |
| | 33 | EP | 724 877 | | Fournier Lab SA | 8/7/1996 | | X+ |
| | 34 | EP | 757 911 | | CLL Pharma | 2/12/1997 | 1 | X+ |
| | 35 | EP. | 770 387 | | B. Braun Melsungen AG | 5/2/1997 | 1 | 1 |
| | 36 | EP | 770 381 | † | Oreal | 5/2/1997 | | X+ |

| Examiner Signature | | Date Considered |
|--------------------|---|-----------------|
| Latanino Oignata | · | |

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

| Please | | | | 1.1 | inaid. | 46:- | |
|--------|--------|-----|-----|-----|--------|------|---------|
| ricase | type a | mus | agn | (マ) | msaue | uns | DOX |



Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

| | Complete if Known |
|------------------------|-------------------|
| Application Number | 9/376,487 |
| Filing Date | August 18, 1999 |
| First Named Inventor | MISHRA |
| Group Art Unit | 1617 |
| Examiner Name | E. Webman |
| Attorney Docket Number | 402090 |

| | | F | oreign Patent Documen | | | · · | Trans | slation |
|----------------------|----------|--------|---------------------------------|--------------|-----------------------------------|---------------------|-------|---------|
| Examiner Initials | Doc. No. | Office | Application or Patent Number | Kind Code | Name of Patentee or Applicant | Date of Publication | Yes | No** |
| | 37 | EP | 814 787 | | AstraZeneca AB | 1/7/1998 | | |
| | · 38 | EP | 1 238 677 | | AstraZeneca AB | 9/11/2002 | | |
| | 39 | FR | 2 265 357 | | ICI Ltd. | 10/24/1975 | | X+ |
| | 40 | FR | 2 617 047 | | Sanofi SA/Fournier Labs. | 12/30/1988 | | X+ |
| | 41 | JP | 55-141407 | | Nattermann A & CIE | 11/5/1980 | | X+ |
| | 42 | JP | 56-167616 | | Green Cross Corp. | 12/23/1981 | | X+ |
| | 43 | JP | 60-208910 | 1.00 | Green Cross Corp. | 10/21/85 | | X+ |
| • | 44 | JP | 63-502117 | | | 8/18/1988 | | X+ |
| | 4 5 | JP | 63-233915 | | Besutaa Res. Inc. | 9/29/1988 | · | X+ |
| | 46 | JP | 1-502590 | | Liposome Tech. Inc. | 9/7/1989 | | X+ |
| 4 | 47 | ΗU | 211 580 | • | Egis Gyogyszergyar Rt. | 12/28/1995 | | X+ |
| | 48 | PCT | WO 85/00011 | | The University of Miami | 1/3/1985 | | |
| | 49 | PCT | WO 87/04592 | | Liposome Tech. Inc. | 8/13/1987 | | |
| | 50 · | PCT | WO 91/04011 | | Riker Labs., Inc. | 4/4/1991 | | |
| | 51 | PCT | WO 93/19736 | | Kabi Pharmacia AB | 10/14/1993 | | |
| | 52 | PCT | WO 94/20072 | | Pharmacia AB | 9/15/1994 | | |
| • | 53 | PCT | WO 96/01637 | | Astra Aktiebolag | 1/25/1996 | | |
| | 54 | PCT | WO 96/19064 | | Xcellenet, Inc. | 6/20/1996 | | |
| | 55 | PCT | WO 96/21439 | | Galephar P.R. Inc. | 7/18/1996 | | |
| - | 56 | PCT | WO 96/29064 | | Zeneca Ltd. | 9/26/1996 | | |
| | 57 | PCT | WO 97/10814 | | Vesifact AG | 3/27/1997 | | |
| | 58 | PCT | WO 97/14407 | | Research Triangle Pharmaceuticals | 4/24/1997 | | |
| | 5 9 | PCT | WO 98/53805 | | Saucy Ltd. | 12/3/1998 | | |
| | 60 | PCT | WO 99/39696 | | Gensia Sicor Inc. | 8/12/1999 | | |
| | 61 | PCT | WO 00/10531 | | RTP Pharma Inc. | 3/2/2000 | | |
| | 62 | PCT | WO 00/24376 | | Abbott Labs. | 5/4/2000 | | |
| | 63 | PCT | WO 00/54588 | | Krusz | 9/21/00 | | |
| | 64 | PCT | WO 00/59471 | | Baxter International, Inc. | 10/12/2000 | | |
| | 6.5 | PCT | WO 00/59472 | | Baxter International, Inc. | 10/12/2000 | | |
| | 66 | PCT | WO 00/78301 | | Kuhnil Pharm. Co. Ltd. | 12/28/2000 | | |
| | 67 | PCT | WO 01/30372 | | BASF Aktiengesellschaft | 5/3/2001 | | Χ÷ |
| | 68 | PCT | WO 02/21517 | | Zeon Corp. | 3/14/2002 | | Χ· |
| | 69 | UK | 2 046 094 | | A. Nattermann & Cie | 11/12/1980 | | |
| | 70 | UK | 2 250 197 | | Egis Gyogyszergyar | 6/3/1992 | | |
| | 71 | UK | 2 298 789 | | Zeneca Ltd. | 9/18/1996 | | ļ . |

| | | | • | |
|--------------------|-----|-------------|-----------------|--|
| | | | | |
| Examiner Signature | | | Date Considered | |
| 1 | i . | | • | |

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

| · . | | ~ 01B |
|---|--|----------|
| | | • |
| | | JAN 2 |
| Please type a plus sign (+) inside this | s box → <mark> </mark> | 2 \$ 200 |
| <u> </u> | (E) | |

Substitute for form 1449A/B/PTO **INFORMATION DISCLOSURE** STATEMENT BY APPLICANT

Complete if Known Application Number 09/376,487 Filing Date August 18, 1999 First Named Inventor **MISHRA** Group Art Unit 1617 E. Webman Examiner Name

(Use as many sheets as necessary)

3 of Attorney Docket Number 402090/SKYEPHARMA

| Examiner | | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item | Tran | slation |
|----------|----------|---|------|----------|
| Initials | Doc. No. | (book, magazine, journal, senal, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published. | Yes | No*+ |
| | 1 | "Diprivan 1% Injection," Physicians' Desk Reference, 1996, pp. 2833-39. | | <u> </u> |
| | 2 | "Diprivan 1% Injection," Physicians' Desk Reference, 1999, pp. 3411-18. | | |
| | 3 | Ardulno, M.J. et al., "Microbial Growth and Endotoxin Production in the Intravenous Anesthetic Propofol", Infection Control and Hospital Epidemiology, Vol. 12, No. 9, September 1991, pp. 535-539. | · . | |
| | 4 | Babl et al., "New Formulations of Propofol in an LCT/MCT Emulsion: Approach to Reduce Pain on Injection", Eur. Hosp. Pharmacy, January 1995, Vol. 1, No. 1, pp. 15-21. | | |
| | 5 | Bangham et al., "Diffusion of Univalent Ions Across the Lamellae of Swollen Phospholipids," J. Mol. Biol., 1965, 13:238-251. | | |
| | 6 | Bennett et al., "Postoperative Infections Traced to Contamination of an Intravenous Anesthetic, Propofol", Vol. 333, No. 3, July 20, 1995, pp. 147-154. | | , |
| | . 7 | Benz et al., "Electrical Capacity of Black Lipid Films and of Lipid Bilayers made from Monolayers," Biochimica et Biophysica Acta, 1975, 394:323-334. | | |
| | . 8 | Bergmann, Ludwig, Der Ultraschall, 5 Aufl., 1949, Struttgart, pp. 551-564 and 665-677. | | Х |
| | 9 | Bittman, Robert, "Sterol-Polyene Antibiotic Complexation: Probe of Membrane Structure," LIPIDS, Vol. 13, No. 10, pp. 686-691 (1978). | | |
| | 10 | Cairns et al., "Tolerance of Mixed Lipid Emulsion in Neonates: Effect of Concentration", Archives of Disease in Childhood, 1996, Vol. 75, p. F113-F116. | | |
| | 11 | Cherney, Leonid S., "Tetracaine Hydroiodide: A Long-Lasting Local Anesthetic Agent for the Relief of Postoperative Pain," Anesthesia and Analgesia, Vol. 42, No. 4, July-Aug. 1963, pp. 477-481. | | |
| | 12 | Crowther et al., "Growth of Microorganisms in Propofol, Thiopental and a 1:1 Mixture of Propofol and Thiopental", Anesth. and Anal., (1996), 82, pp. 475-478. | | |
| | 13 | Cudd et al., "Liposomes Injected Intravenously into Mice Associate with Liver Mitochondria," Biochimica et Biophysica Acta, (1984), 774:169-180. | | |
| | 14 | De Sommer et al., "A Comparative Study on the Effects of Proposol in Emulsion and Intralipid [®] on Fat Metabolism," Acta Anesthesiologica Belgica, Vol. 41, No. 2, 1990, pp. 133-138. | | |
| | 15 | Dewandre et al., "A Comparison of the 2% and 1% Formulations of Propofol During Anaesthesia for Craniotomy," Anesthesia, 1994, Vol. 49, pp. 8-12. | | |
| | 16 | Doenicke, A.W. et al., "Pharmacokinetics and Pharmacodynamics of Propofol in a New Solvent", Anesth. Analg., (1997), 85:1399-403. | | |
| | .17 | Doenicke, A.W. et al., "Reducing Pain During Propofol Injection: The Role of the Solvent", Anesth. Analg., (1996), 82:472-4. | | |

| | | | 1 0-4- | |
|-----------|---|---------------------------------------|--------------|---------------------------------------|
| Examiner | | | Date | |
| | , | · · · · · · · · · · · · · · · · · · · | | |
| Signature | 1 | | l Considered | · · · · · · · · · · · · · · · · · · · |
| Cignature | | | | |

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

⁺ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

| | Please | type a | a plus | sign | (+) | inside | this | ьо |
|--|--------|--------|--------|------|-----|--------|------|----|
|--|--------|--------|--------|------|-----|--------|------|----|

| | PE | |
|--------------|----------|-----|
| × ≯ ⊞ | • | 5 |
| JAN | 2 6 2003 | * |
| | | بنج |
| 125 | A C | ζ. |

INFORMATION DISCESSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary) Sheet

| Complete if Known | | | | |
|-----------------------|-------------------|--|--|--|
| Application Number | 09/376,487 | | | |
| Filing Date | August 18, 1999 | | | |
| First Named Inventor | MISHRA | | | |
| Group Art Unit | 1617 | | | |
| Examiner Name | E. Webman | | | |
| Attomey Docket Number | 402090/SKYEPHARMA | | | |

| | | OTHER - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item | - | 1-41 |
|----------------------|----------|---|-----|-----------------|
| Examiner Initials | Doc. No. | (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s) | Yes | slation No*+ |
| | 18 | publisher, city and/or country where published. Eddleston et al., "The Effect on Serum Lipid Concentrations of a Prolonged Infusion of Propofol – Hypertriglyceridaemia Associated with Propofol Administration," Intensive Care Med., (1991), 17:424-426. | 163 | No. |
| | 19 | Ewart et al., "Forum: 2% Propofol for Sedation in the Intensive Care Unit, A Feasibility Study", Anaesthesia, February 1992, Vol. 47, No. 2, pp. 146-148. | | |
| | 20 | Freeman, Andrew B., *A Technique for Reducing Pain Associated with Propofol Administration,* Anesth. Analg., 1992, 74:311-319, | | |
| | 21 | Ghouri et al., "Effect of Flumazenil on Recovery after Midazolam and Propofol Sedation", Anesthesiology, (1994), 81:333-339. | | · |
| | 22 | Goodman & Gillman's The Pharmacological Basis of Therapeutics, 7 th Ed., MacMillan Publishing Co., New York, 1985. p.312. | | |
| , | 23 | Gottardis et al., Effect of Prolonged Sedation with Propofol on Serum Triglyceride and Cholesterol Concentrations, British J. Anaesthesia, (1989) 62:393-396. | | |
| | 24 | Gregoriadis, Gregory, "The Carrier Potential of Liposomes in Biology and Medicine", The New England Journal of Medicine, September 23, 1976, Vol. 295, pp. 704-710. | | |
| | 25 | Haung et al., "Interaction of the N-terminus of Sterol Carrier Protein 2 with Membranes: Role of Membrane Curvature," Biochem. J., (1999), 344:593-603. | | |
| _ | 26 | Haynes et al. "Ultra-Long Duration Local Anesthesia Produced by Intra-Dermal Injection of Lecithin-Coated Methoxyflurane Microdroplets", Proceed. Intern. Symp. Control. Rel. Bioact. Mater., (1987), 14:293-294 (Extended abstract) | | |
| | 27 | Haynes et al., "Ultra-long-duration Local Anesthesia Produced by Injection of Lecithin-coated Methoxyfluorene Microdroplets", Anesthesiology, November 1985, Vol. 63, No. 5, pp. 490-499. | | |
| | 28 | Haynes, Duncan H., "Divalent Cation-Ligand Interactions of Phospholipid Membranes: Equilibria and Kinetics," Metal-Ligand Interactions in Organic Chemistry and Biochemistry, Pullman and Goldblum, Eds., part 2, ©1977, pp. 189-212 | | |
| | 29 | King et al., "Lidocaine for the Prevention of Pain Due to Injection of Propofol," Anesth. Analg., 1992, 74:246-249. | | |
| | 30 | Kirkpatrick et al., "Local Anesthetic Efficacy of Methoxyflurane Microdroplets in Man," Anesthesiology, 1987, 67(3A):A254, Abstract only. | | |
| _ | 3 1 | Lindholm, Marianne, "Critically III Patients and Fat Emulsions," Minerva Anesthesiology, 1992, Vol. 58, No. 10, pp. 875-879. | | |
| | 32 | Mangar et al., "Tourniquet at 50 mm Hg Followed by Intravenous Lidocaine Diminishes Hand Pain Associated with Propofol Injection", Anesth. Analg., (1992), 74:250-252. | | · |
| | 33 | Mirakhur et al., "Induction Characteristics of Propofol in Children: Comparison with Thiopenttone", Anesthesia, (1998), 43:593-598. | | |
| | 34 | Mishra et al., "Scientifically Speaking: Novel Injectable Formulations of Water-insoluble Drugs", Controlled Release Newsletter, Vol. 17, Issue 2, June 2000, pp.21-30 | | · |
| | 35 | Nichols, Ronald Lee, "Bacterial Contamination of an Anesthetic Agent," New Engl. J. Med., (1995), 333(3), 184-185. | | |

| Examiner | • | Date | |
|-----------|---|------------|--|
| Signature | | Considered | |

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

⁺ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

JAN 2 4 2003

Substitute for form 1449A/B/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary) of

| Complete if Known | | | | | | | |
|------------------------|-------------------|--|--|--|--|--|--|
| Application Number | 09/376,487 | | | | | | |
| Filing Date | August 18, 1999 | | | | | | |
| First Named Inventor | MISHRA | | | | | | |
| Group Art Unit | 1617 | | | | | | |
| Examiner Name | E. Webman | | | | | | |
| Attorney Docket Number | 402090/SKYEPHARMA | | | | | | |

| | | OTHER - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item | T | slation |
|---------------------------|----------|---|-----|---------|
| Examiner Initials | Doc. No. | (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published. | Yes | No** |
| 36 Rompp, "Emulsion", Che | | Rompp, "Emulsion", Chemie-Lexikon, 2 Aufl., Bd. 1, 1950, Stichwort. | | |
| | 37 | Ross, et al., "Aqueous Solutions of Surface-Active Solutes", Colloidal Systems and Interfaces, © 1988, p. 148-151 | | X |
| | 38 | Sande et al., "Antimicrobial Agents: Antifungal and Antiviral Agents," p. 1219-1222. | | |
| | 39 | Sandstrom et al., "Structured Triglycerides Were Well Tolerated and Induced Increased Whole Body Fat Oxidation Compared With Long-Chain Triglycerides in Postoperative Patients," Journal of Parenteral and Enteral Nutrition, (1995), 19(5):381-6. | | |
| | 40 | Sklar, Grant E., "Propofol and Postoperative Infections," The Annals of Pharmacotherapy, (1997), 31:1521-3. | | |
| | 41 | Smith et al., "Propofol: An Update on its Clinical Use," Anesthesiology, Oct. 1994, Vol. 81, No. 4, pp. 1005-1043. | | |
| | 42 | Sosis et al., "Growth of Staphylococcus aureus in Four Intravenous Anesthetics," Anesth. Anal., (1993), Vol. 77, pp. 766-768 | | |
| | 4 3 | Sosis et al., "Propofol, but not Thiopental, Supports the Growth of Candida albicans," Anesth. Anal., (1995), Vol. 81, pp. 132-134. | | |
| | 4 4 | Stark, et al., "A review of the safety and tolerance of propofol ('Diprivan')", Postgraduate Medical Journal, 1985, Vol. 61, Suppl. 3, pp. 152-156. | | |
| | 4 5 | Stenz et al., "A new physiologically approached in vitro test for quick evaluation of the hemolytic activity of surfactants," Pharmazie, (1996), 51(5), pp. 283-287. | | |
| | 46 | Tessler et al., "Growth curves of Staphyloccoccus aureus, Candida albicans, and Moraxella osloensis in propofol and other media", Can. J. Anaesth., 1992, 39 (5), pp. 509-511. | | |
| | 47 | White et al., "Sedative Infusions During Local and Regional Anesthesia: A Comparison of Midazolam and Propofol", J. Clin. Anesth., Jan/Feb 1991, Vol. 3, pp. 32-39. | | |
| | 48 | Wu et al., "Pharmacokinetics of Methoxyflurane after its Intra-dermal Injection as Lecithin-Coated Microparticles", Journal of Controlled Release, 1989, Vol. 9, pp. 1-12. | | |
| | | | | |
| | | | | |

| Examiner | | Date | | |
|-------------|---------|------------|------|--|
| Signature - | | Considered | | |
| | <u></u> | | | |

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of

| Complete if Known | | | | | | |
|------------------------|-------------------|---|--|--|--|--|
| Application Number | 09/376,487 | ┨ | | | | |
| Filing Date | August 18, 1999 | ٦ | | | | |
| First Named Inventor | MISHRA | ٦ | | | | |
| Group Art Unit | 1617 | ٦ | | | | |
| Examiner Name | E. Webman | ٦ | | | | |
| Attorney Docket Number | 402090/SKYEPHARMA | ┨ | | | | |

| | | | | J.S. PATENT DOCUMENTS | | | |
|-------------------|----------|---------------------------------|--------------|-------------------------------|------------------------|---------------------------------------|--|
| | | U.S. Patent Docum | ent | | | | |
| Examiner Initials | Doc. No. | Application or Patent Number | Kind Code | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriate | |
| | 1 | 6,028,108 | | George | 2/22/2000 | | |
| | 2 | 6,140,374 | · | May et al. | 10/31/2000 | | |
| | 3 | 6,140,373 | | May et al. | 10/31/2000 | | |
| | 4 | 6,147,122 | | Mirejovsky et al. | 11/14/2000 | | |
| | 5 | 6,177,477 | | George et al. | 1/23/2001 | · · · · · · · · · · · · · · · · · · · | |
| | 6 | 6,197,323 | | Georgieff | 3/6/2001 | | |
| | 7 | 2001/0008889 | | Caruso et al. | 7/19/2001 | | |
| | 8 | 6,284,267 | | Aneja | 9/4/2001 | | |
| | 9 | 6,291,013 | | Gibson et al. | 9/18/2001 | · | |
| | 10 | 2001/0025035 | | Stella et al. | 9/27/2001 | · | |
| | . 11 | 2001/0041923 | | Dobak, III | 11/15/2001 | | |
| | 12 | 6,322,810 | | Alkan-Onyuksel et al. | 11/27/2001 | • | |
| | 13 | 2001/0051595 | | Lyons et al. | 12/13/2001 | | |
| | 14 | 2002/0002704 | | Davis et al. | 1/3/2002 | | |
| , | 15 | 2002/0003179 | | Verhoff et al. | 1/10/2002 | | |
| | 16 | 2002/0016373 | | Bieniarz et al. | 2/7/2002 | · | |
| | 17 | 2002/0017296 | | Hickle | 2/14/2002 | | |
| | . 18 | 2002/0017299 | | Hickle | 2/14/2002 | | |
| | 19 | 2002/0017300 | | Hickle et al. | 2/14/2002 | | |
| | 20 | 2002/0022667 | | Pace et al. | 2/21/2002 | | |
| | 21 | 2002/0025337 | | Illum et al. | 2/28/2002 | | |
| | 22 | 2002/0032171 | | Chen et al. | 3/14/2002 | | |
| | 23 | 2002/0035141 | | Attala | 3/21/2002 | | |
| | 24 | 2002/0035161 | | Segura et al. | 3/21/2002 | , | |
| | 25 | 2002/0037933 | | Basu et al. | 3/28/2002 | | |
| | 26 | 6,365,190 | | Gordon et al. | 4/2/2002 | | |
| | 27 | 6,368,619 | | New et al. | 4/9/2002 | | |
| · | 28 | 2002/0047058 | | Verhoff et al. | 4/25/2002 | | |
| | 29 | 2002/0058009 | | Bartus et al. | 5/16/2002 | | |
| | 30 | 2002/0068764 | | Franks et al. | 6/6/2002 | I | |
| | 3 1 | 2002/0071852 | | Deckers et al. | 6/13/2002 | | |
| | 32 | 2002/0082252 | | Hochman | 6/27/2002 | | |
| | 33 | 6,413,527 | | Simonnet et al. | 7/2/2002 | | |
| | 34 | 6,419,949 | | Gasco | 7/16/2002 | | |
| | 35 | 2002/0102217 | | Klaveness et al. | 8/1/2002 | | |
| | 36 | 2002/0102216 | | Lanza et al. | 8/1/2002 | | |
| | 37 | 2002/0102215 | | Klaveness et al. | 8/1/2002 | | |
| | | | | | | | |

| | | |
|--------------------|---------------------|--|
| Examiner Signature | Date Considered | |
| | | |

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

⁺ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

JAN 2 4 2003

Substitute for form 1449A/B/PTO

TRADENIA PO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet of

| Complete if Known | | | | | | | | |
|------------------------|-------------------|--|--|--|--|--|--|--|
| Application Number | 09/376,487 | | | | | | | |
| Filing Date | August 18, 1999 | | | | | | | |
| First Named Inventor | MISHRA | | | | | | | |
| Group Art Unit | 1617 | | | | | | | |
| Examiner Name | E. Webman | | | | | | | |
| Attorney Docket Number | 402090/SKYEPHARMA | | | | | | | |

| | | · · · · · · · · · · · · · · · · · · · | U | .S. PATENT DOCUMENTS | | |
|----------------------|------|---------------------------------------|-----|-------------------------------|---------------------|----------------|
| Examiner Initials | | | | Name of Patentee or Applicant | Date of Publication | Filing Date If |
| | 38 | 2002/0102281 | | Auberger et al. | 8/1/2002 | |
| | 39 | 2002/0107291 | | De Tommaso | 8/8/2002 | |
| | 40 | 2002/0107265 | | Chen et al. | 8/8/2002 | |
| | 41 | 6,433,040 | T . | Dellamary et al. | 8/13/2002 | |
| | 42 | 6,436,367 | | Modi | 8/20/2002 | |
| | 43 | 6,436,430 | | Mulye | 8/20/2002 | |
| | . 44 | 2002/0115609 | | Onyuksel et al. | 8/22/2002 | |
| | 4 5 | 6,440,456 | | Nguyen et al. | 8/27/2002 | |
| | 46 | 6,440,493 | . • | Gibson et al. | 8/27/2002 | |
| | 47 | 2002/0120015 | | Dennis et al. | 8/29/2002 | |
| | 48 | 2002/0120002 | | Baker et al. | 8/29/2002 | |
| | 49 | 6,444,859 | | Bieniarz et al. | 9/3/2002 | |
| | 50 | 2002/0128698 | | Dobak, III et al. | 9/12/2002 | |
| | 5 1. | 6,451,339 | | Patel et al. | 9/17/2002 | |
| | 52 | 2002/0142093 | | Gibson et al. | 10/3/2002 | |
| | 53 | 6,464,987 | | Fanara et al. | 10/15/2002 | · |
| | 54 | 2002/0150621 | | Kohane et al. | 10/17/2002 | |
| | 55 | 6,469,069 | | Mirejovsky et al. | 10/22/2002 | |
| | 56 | 2002/0160043 | | Coleman | 10/31/2002 | |
| | 57 | 6,475,506 | | Inoue et al. | 11/5/2002 | |
| | 58 | 2002/0173547 | | Jones et al. | 11/21/2002 | |
| | | | | | | |
| | | | | | | |

| | | | · · · · · · · · · · · · · · · · · · · | FOREIG | N PATENT DOCUMENTS | | | |
|-------------------|----------|-------------------------|---------------------------------------|--------------|-------------------------------|---------------------|-----|------|
| | | Foreign Patent Document | | | | Translation | | |
| Examiner Initials | Doc. No. | Office | Application or Patent Number | Kind Code | Name of Patentee or Applicant | Date of Publication | Yes | No*+ |
| | 59 | JP | 10-251142 | | Michael | 9/22/1998 | | X+ |
| | 60 | JP | 2000-119177 | | Torii Yakuhin KK | 4/25/2000 | | X+ |
| | 61 | JP | 2002-179562 | | Towa Yakuhin KK | 6/26/2002 | | X+ |
| | 62 | PCT | WO 96/32135 | | Farmarc Nederland BV | 10/17/1996 | | 1 |
| | 63 | PCT | WO 02/074200 | | Cydex, Inc. | 9/26/2002 | | Ī. |
| | 64 | UK | 2 359 747 | | Maelor Pharmaceuticals Ltd. | 9/5/2001 | · . | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | • | |
| | | | | | | | | |

| Examiner Signature | D | Date Considered | | |
|--|-------|-----------------|--|---|
| <u>1 </u> | | i | | _ |

A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).